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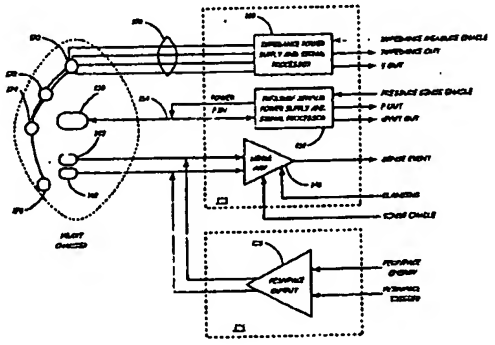
(54) Title: IMPLANTABLE MEDICAL DEVICE FOR TREATING CARDIAC MECHANICAL DYSFUNCTION BY ELECTRICAL STIMULATION



(57) Abstract: An implantable stimulator and monitor measures a group of heart failure parameters indicative of the state of heart failure employing EGM signals, measures of blood pressure including absolute pressure P, developed pressure (DP = systolic P diastolic P), and/or dP/dt, and measures of heart chamber volume (V) over one or more cardiac cycles. These parameters include: (1) relaxation or contraction time constant tau (τ); (2) mechanical restitution (MR), ie., the mechanical response of a heart chamber to premature stimuli applied to the heart chamber; (3) recirculation fraction (RF), i.e., the rate of decay of PESP effects over a series of the heart cycles; and (4) end systolic elastance (E_{ES}), i.e., the ratios of end systolic blood pressure P to volume V. These heart failure parameters are determined periodically regardless of patient posture and activity level. The physician can determine whether a particular therapy is appropriate, prescribe the therapy for a period of time while again accumulating the stored patient data for a later review and assessment to determine whether the applied therapy is beneficial or not, thereby enabling periodic changes in therapy, if appropriate. Drug therapies and electrical stimulation therapies, including PESP stimulation, and pacing therapies including single chamber, dual chamber and multi-chamber (bi-atrial and/or bi-ventricular) pacing can be delivered. In patient's prone to malignant tachyarrhythmias, the assessment of heart failure state can be taken into account in setting parameters of detection or classification of tachyarrhythmias and the therapies that are delivered.

WO 02/053026 A3

AMENDED CLAIMS

[received by the International Bureau on 22 November 2002 (22.11.2002); original claims 1-16 amended; remaining claims unchanged (9 pages)]

1. In an implantable medical device, a system for monitoring the state of heart failure of the heart of a heart failure patient and delivering a therapy characterized by:

pulse generating means (150) for selectively generating and applying a pacing pulse to at least one heart chamber to effect a contraction of the heart chamber commencing a heart cycle and for selectively generating and applying an extrasystolic electrical stimulus to the at least one heart chamber at the time out of an extrasystolic escape interval to induce post-extrasystolic potentiation increasing the strength of contraction of the heart chamber;

electrical signal sense means (108) for sensing the electrical signals of the heart in said at least one heart chamber and providing a sense event signal signifying the contraction of the heart commencing a heart cycle;

heart chamber volume measuring means (170, 172, 174, 176) for measuring the volume of a heart chamber over at least a portion of a heart cycle and providing a chamber volume value;

blood pressure measuring means (160) for measuring blood pressure within a heart chamber over at least a portion of a heart cycle and providing a blood pressure value;

parameter deriving means (162) for selectively enabling operation of said pulse generating means, said electrical signal sense means, said heart chamber volume measuring means, and said blood pressure measuring means for periodically deriving a plurality of heart failure parameters signifying the state of heart failure from selected measured values of chamber volume and blood pressure, the heart failure parameters including:

a tau parameter representing one of a relaxation and contraction time constant of the heart chamber,

a mechanical restitution parameter representing the mechanical response of a heart chamber to electrical stimuli applied to the heart chamber prematurely at differing times during a plurality of heart cycles,

a recirculation fraction parameter representing the increase in strength of a contraction of the heart chamber in response to an electrical stimuli applied to the

heart chamber during a heart cycle and the rate of decay of the increase in strength of successive contractions of the heart chamber over a series of heart cycles; and

an elastance parameter representing the slope of plotted sets of end systolic blood pressure versus end systolic chamber volume over a plurality of heart cycles; and

therapy delivery means (106) responsive to a determined heart failure parameter for operating said pulse generating means in a therapy delivery mode to increase the strength of contraction of the patient's heart and improve the heart failure state.

2. The implantable medical device of Claim 1, characterized in that said therapy delivery means is further characterized by:

means for establishing a therapy delay timed from a pacing pulse or sensed event that lapses within the refractory period of the heart but outside the vulnerable period of the heart, a therapy burst pulse number X, and a therapy pulse separation interval between each pulse of a therapy burst of X pulses;

means for timing out the therapy delay and triggering the delivery of one or more burst pacing pulse within the refractory period; and

means for timing out the pulse separation interval for each of the remaining burst pacing pulses and triggering the delivery of at least one burst pacing pulse outside of the refractory period to increase the strength of contraction of the patient's heart.

3. The implantable medical device of Claim 1, characterized in that the tau parameter deriving means is further characterized by:

means for operating said blood pressure measuring means to make N blood pressure (P) and rate of change (dP/dt) measurements in the heart chamber at a predetermined sample rate over a heart cycle following a natural, intrinsic, or paced depolarization of the heart chamber;

means for determining dP/dt MIN and the time of dP/dtMIN during the heart cycle; and

means for deriving the tau parameter at the time of dP/dt MIN as a function of a set of samples of pressure P and dP/dt within a time window measured from the time of dP/dt MIN.

4. The implantable medical device of Claim 1, characterized in that the recirculation fraction parameter deriving means is further characterized by:

means for operating said pulse generating means to provide fixed rate pacing directly or indirectly to a heart chamber to stabilize the heart rate of the heart chamber at a steady state (SS) over a first predetermined number of paced SS heart cycles;

means for operating said pulse generating means for providing extrasystolic (ES) stimulation to a heart chamber after an extrasystolic interval timed from a pace pulse during each at least one paced ES heart cycle;

means for operating said blood pressure measuring means to make N blood pressure (P) and rate of change (dP/dt) measurements in the heart chamber that is depolarized directly or indirectly by the delivered pacing pulses at a predetermined sample rate over at least a portion of a second predetermined number of paced heart cycles following the last paced ES heart cycle;

means for determining maximum blood pressure rate of change (dP/dt MAX (ES)) during each of the second predetermined number of paced heart cycles following the last paced ES heart cycle, the determined dP/dt MAX (ES) values and the paced heart cycle numbers comprising an RF parameter data set,

whereby each determined dP/dt MAX (ES) value of each stored RF parameter data set can be plotted in relation to the paced heart cycle number to exhibit the exponential decay of the dP/dt MAX (ES) values over time that reflects the decay in the PESP effect in the heart chamber after delivery of the ES stimulation.

5. The implantable medical device of Claim 4, characterized in that the recirculation fraction parameter deriving means is further characterized by:

means for operating said blood pressure measuring means to make N blood pressure (P) and rate of change (dP/dt) measurements in the heart chamber that is depolarized directly or indirectly by the delivered pacing pulse at a predetermined sample rate during at least one SS paced heart cycle;

means for determining a maximum blood pressure rate of change (dP/dt MAX (SS)) during the SS heart cycle; and

means for determining that the at least one determined dP/dt MAX (ES) value exceeds the dP/dt MAX (SS) value.

6. The implantable medical device of Claim 1, characterized in that the end systolic elastance parameter deriving means for deriving the slope of plotted sets of end systolic blood pressure versus end systolic chamber volume over a plurality of heart cycles is further characterized by:

(a) means for operating said blood pressure measuring means and said heart chamber volume measuring means to make N blood pressure (P) measurements and N volume (V) measurements of the heart chamber at a predetermined sample rate over a series of heart cycles following a natural, intrinsic, or paced depolarization of the heart chamber;

(b) means for selecting the end systolic blood pressure (P_{ES}) measurements and end systolic volume (V_{ES}) measurements at the end systolic point in each heart cycle;

(c) means for establishing a threshold correlation coefficient R^2;

(d) means for accumulating n sets of end systolic [P_{ES}, V_{ES}] data points;

(e) means for performing a linear regression of the "n" sets of [P_{ES}, V_{ES}] data points to derive the slope of the sampled data set, a sample correlation coefficient R and a sample squared correlation coefficient R^2;

(f) means for comparing the sample squared correlation coefficient R^2 to the threshold squared correlation coefficient R^2; and

(g) means for storing the derived slope as the end systolic elastance if the sample squared correlation coefficient R^2 exceeds the threshold squared correlation coefficient R^2.

7. The implantable medical device of Claim 6, characterized in that the end systolic elastance parameter deriving means is further characterized by:

means operable if the sample squared correlation coefficient R^2 does not exceed the threshold squared correlation coefficient R^2 for continuously operating

means (a) - (f) to develop the "n" sets of [P_{ES} , V_{ES}] data points where the oldest set of [P_{ES} , V_{ES}] data points is replaced by the newest set of [P_{ES} , V_{ES}] data points on a FIFO basis until the sample squared correlation coefficient R^2 exceeds the threshold squared correlation coefficient R^2 and for then operating means (g) for storing the derived slope as the end systolic elastance when the sample squared correlation coefficient R^2 exceeds the threshold squared correlation coefficient R^2.

8. The implantable medical device of Claim 1, characterized in that the mechanical restitution parameter deriving means is further characterized by:

means for operating said pulse generating means to provide fixed rate pacing directly or indirectly to a heart chamber to stabilize the heart rate of the heart chamber at a steady state (SS) over a first predetermined number of paced SS heart cycles;

means for operating said blood pressure measuring means to make N blood pressure measurements P and dP/dt in the heart chamber that is depolarized directly or indirectly by the delivered pacing pulse at a predetermined sample rate during at least one SS paced heart cycle;

means for determining maximum blood pressure rate of change (dP/dt MAX (SS)) during the SS heart cycle;

means for operating said pulse generating means to provide fixed rate pacing and for providing extrasystolic (ES) stimulation at differing timed extrasystolic intervals timed from a pace pulse during each of a second predetermined number of paced ES heart cycles;

means for operating said blood pressure measuring means to make N blood pressure measurements P and dP/dt in the heart chamber at a predetermined sample rate over at least a portion of each of the second predetermined number of paced ES heart cycles;

means for determining maximum blood pressure rate of change (dP/dt MAX (ES)) during each ES heart cycle; and

means for processing each determined dP/dt MAX (ES) with respect to the dP/dt MAX (SS) to derive mechanical restitution data sets from which the time constant of systolic restitution tc_{mrt} is derived.

9. In an implantable medical device, a system for monitoring the state of heart failure as a function of the mechanical restitution of the heart of a heart failure patient and delivering a therapy characterized by:

means for determining a stable cardiac cycle of a heart chamber having a heart cycle escape interval;

means for timing out an extrasystolic escape interval during the heart cycle escape interval;

pulse generating means for selectively generating and applying an extrasystolic electrical stimulus to the heart chamber at the time out of the extrasystolic escape interval to induce post-extrasystolic potentiation increasing the strength of contraction of the heart chamber;

blood pressure measuring means for measuring blood pressure within a heart chamber over at least a portion of a heart cycle and providing a blood pressure value;

mechanical restitution parameter deriving means for selectively enabling operation of said pulse generating means and said blood pressure measuring means for periodically deriving a mechanical restitution parameter representing the mechanical response of a heart chamber to the electrical stimuli applied to the heart chamber prematurely at differing extrasystolic escape intervals during a plurality of heart cycles; and

therapy delivery means responsive to a determined heart failure parameter for operating said pulse generating means in a therapy delivery mode to increase the strength of contraction of the patient's heart and improve the heart failure state.

10. The implantable medical device of Claim 9, characterized in that said therapy delivery means is further characterized by:

means for establishing a therapy delay timed from a pacing pulse or sensed event that lapses within the refractory period of the heart but outside the vulnerable period of the heart, a therapy burst pulse number X, and a therapy pulse separation interval between each pulse of a therapy burst of X pulses;

means for timing out the therapy delay and triggering the delivery of one or more burst pacing pulse within the refractory period; and

means for timing out the pulse separation interval for each of the remaining burst pacing pulses and triggering the delivery of at least one burst pacing pulse outside of the refractory period to increase the strength of contraction of the patient's heart.

11. In an implantable medical device, a system for monitoring the state of heart failure as a function of the mechanical restitution of the heart of a heart failure patient and delivering a therapy characterized by:

pacing pulse generating means for selectively generating and applying a pacing pulse to at least one heart chamber to effect a contraction of the heart chamber commencing a paced heart cycle;

extrasystolic escape interval timing means for timing an extrasystolic escape interval from a previously generated and applied pacing pulse;

extrasystolic stimuli generating means for selectively generating and applying electrical stimuli to the at least one heart chamber at the time out of the extrasystolic escape interval to induce post-extrasystolic potentiation increasing the strength of contraction of the heart chamber;

blood pressure measuring means for measuring blood pressure within a heart chamber over at least a portion of a heart cycle and providing a blood pressure value;

mechanical restitution parameter deriving means for selectively enabling operation of said pacing pulse generating means to generate and apply pacing pulses to the heart chamber, said extrasystolic escape interval timing means to time out a predetermined extrasystolic escape interval following predetermined applied pacing pulses, said extrasystolic stimuli generating means to generate and apply extrasystolic stimuli to the heart chamber at the time out of each extrasystolic escape interval, and said blood pressure measuring means to determine a blood pressure value representing the force of contraction of the heart chamber following each applied extrasystolic stimuli, whereby a data set of such determined blood pressure values correlated to the extrasystolic escape intervals is derived and represents the mechanical restitution parameter of the heart chamber; and

therapy delivery means responsive to a determined heart failure parameter for operating said pulse generating means in a therapy delivery mode to increase the strength of contraction of the patient's heart and improve the heart failure state.

12. The implantable medical device of Claim 11, characterized in that said therapy delivery means is further characterized by:

means for establishing a therapy delay timed from a pacing pulse or sensed event that lapses within the refractory period of the heart but outside the vulnerable period of the heart, a therapy burst pulse number X, and a therapy pulse separation interval between each pulse of a therapy burst of X pulses;

means for timing out the therapy delay and triggering the delivery of one or more burst pacing pulse within the refractory period; and

means for timing out the pulse separation interval for each of the remaining burst pacing pulses and triggering the delivery of at least one burst pacing pulse outside of the refractory period to increase the strength of contraction of the patient's heart.

13. The implantable medical device of Claim 11, characterized in that said determined blood pressure value is a maximal systolic blood pressure value, and said mechanical restitution parameter deriving means is further characterized by:

means for enabling said blood pressure measuring means to sample blood pressure in the heart chamber during a paced heart cycle in which extrasystolic stimuli are not applied to the heart chamber to derive a reference maximal systolic blood pressure value and to sample blood pressure in the heart chamber during each paced heart cycle following each applied extrasystolic stimulus to derive a plurality of extrasystolic maximal systolic blood pressure values; and

means for normalizing each of said extrasystolic maximal systolic blood pressure values to said reference maximal systolic blood pressure value to derive a data set of normalized extrasystolic maximal systolic blood pressure values.

14. The implantable medical device of Claim 11, characterized in that said reference and extrasystolic maximal systolic blood pressure values are sampled blood pressure rate of change values.

15. The implantable medical device of Claim 11, characterized in that said determined blood pressure value is a minimal diastolic blood pressure value, and said mechanical restitution parameter deriving means is further characterized by:

means for enabling said blood pressure measuring means to sample blood pressure in the heart chamber during a paced heart cycle in which extrasystolic stimuli are not applied to the heart chamber to derive a reference minimal diastolic blood pressure value and to sample blood pressure in the heart chamber during each paced heart cycle following each applied extrasystolic stimulus to derive a plurality of extrasystolic minimal diastolic blood pressure values; and

means for normalizing each of said extrasystolic minimal diastolic blood pressure values to said reference minimal diastolic blood pressure value.

16. The implantable medical device of Claim 15, characterized in that said reference and extrasystolic minimal diastolic blood pressure values are sampled blood pressure rate of change values.